

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

Deborah Anne Ehlers,

Plaintiff,

Civ. No. 06-3122 (RHK/AJB)
**MEMORANDUM OPINION
AND ORDER**

v.

Siemens Medical Solutions, USA, Inc.,

Defendant.

Harry A. Sieben, Jr., Jeffrey S. Sieben, Michael M. Miller, Sieben, Grose, Von Holtum & Carey, Ltd., Minneapolis, Minnesota, for Plaintiff.

Adam D. Hirtz, Bryce J. Bartlett, Christine F. Miller, Husch Blackwell Sanders, LLP, St. Louis, Missouri, Sheila T. Kerwin, Christine M. Mennen, Brian N. Johnson, Halleland Lewis Nilan & Johnson, P.A., Minneapolis, Minnesota, for Defendant.

INTRODUCTION

Plaintiff Deborah Ehlers filed this product-liability action against Defendant Siemens Medical Solutions USA, Inc. (“Siemens”) after sustaining a crushed ankle in an on-the-job accident. She claims that a design defect in an x-ray machine manufactured by Siemens caused her injury. Siemens denies liability and seeks summary judgment. For the reasons set forth below, the Court will grant the Motion.¹

¹ This Motion was argued at the William Mitchell College of Law in St. Paul, Minnesota. The Court expresses its appreciation to the law school for hosting the hearing and to counsel for their participation.

BACKGROUND

Siemens is the United States distributor of institutional x-ray machines designed and manufactured by Siemens AG, a German company. In August 2003, it sold a C-arm x-ray machine (“x-ray machine”) to Abbott Northwestern Hospital (“Abbott”). (Hirtz Aff. Ex. A-6; Exs. A-3-5.) Ehlers worked at Abbott as a nurse in the catheterization labs that used this x-ray machine. (Id. at 17-20, 25, 31.) In designing this x-ray machine, Siemens followed a comprehensive product-risk-management process. (Id. Ex. A-19; Ex. A-12 at 68-69.) The x-ray machine was equipped with a number of safety features intended to prevent collisions during unit movements.² (Id. Ex. A-11.)

In April 2005, Siemens installed the x-ray machine at Abbott. (Id. Ex. A-1 at 46, 48, 50; Ex. A-7 at 25.) It provided staff at Abbott with extensive training on the operation and safety features of the x-ray machine. (Id. Ex. A-8 at 53-54; A-9 at 21-24; B-1.) In particular, Siemens asked Abbott to choose no more than six staff members (the “core group”) to receive training on the x-ray machine. (Id. Ex. B-1; Ex. A-9 at 74-76.) Abbott’s core group was made up of radiology technicians, including Carolyn Linde-Flaherty and Tracy Coombs. (Id. Ex. C at ¶ 7.) It also trained the physicians separately

² Such features included: (1) “Dead man’s grip” (a joystick located on a control console that dictates the movements of the C-arm); (2) Collision computer (constantly calculates all possible collisions between known, fixed objects in the room such as the patient table); (3) Speed reduction (speed is automatically reduced for movements in the collision area around the patient and movement is stopped, if necessary); (4) Collision sensors (touch-point sensors are located on the intensifier/flat detector and collimator of the C-arm and will automatically stop the movement when the sensors are contacted); (5) Emergency stop buttons (C-arm movements can be stopped immediately by pressing one of the several stop buttons located on the x-ray machine and around the room); and (6) Warning sounds (if a C-arm is moved into the collision zone, a warning sound is emitted and movement is slowed down, but it does not sound during normal movements). (Hirtz Aff. Ex. A-11.)

from the core group. (Id. Ex. C.) Upon completion of the core-group training, the participants were expected to train other hospital staff who would be working with and around the x-ray machines.³ (Id. Ex. A-8 at 77; A-9 at 30; Ex. B-1.) Abbott did not train Ehlers on the operation or safety of the x-ray machine. (Id. Ex. A-1 at 38-39; 46-48.) It did, however, train her on transferring patients to an x-ray table. (Id. at 39, 46.)

Siemens advised the core group and the physicians that the x-ray machine should be placed in the “patient transfer position” when transferring a patient to an x-ray table. (Id. Ex. A-9 at 76-77; 86-87.) The patient-transfer position refers to a safety-position setting that moves the C-arm of the x-ray machine approximately six feet away from the head of the x-ray table. (Id. Ex. D.) The x-ray machine also included an operator manual which instructed the user to put the x-ray machine in the patient-transfer position during patient transfers. (Id. Ex. A-11.) Siemens also advised the user that it may be necessary to move the control console during a patient transfer to “make sure no unit movements are initiated inadvertently.” (Id.) An operator can easily move the x-ray machine into the patient-transfer position by selecting this option on the system monitor. (Id.) Once the patient-transfer position is selected, the x-ray machine automatically moves to that position. (Id. Ex. A-12 at 25; Ex. A-5 at Part I.) This process takes no more than twenty to thirty seconds. (Id. Ex. A-13 at 146-47; Ex. A-12 at 36-37; Ex. A-5 at Part I.)

On May 5, 2005, Ehlers suffered a broken ankle when the C-arm of the x-ray machine crushed her right foot while she was standing at the head of the x-ray table and

³ Siemens offered to train hospital staff outside the core group, but Abbott did not request this additional training. (Hirtz Aff. Ex. A-8 at 82-83; Ex. A-9.)

assisting other hospital staff with transferring a patient from a gurney to the x-ray table. (Id. Ex. A-10; Ex. A-1 at 70.) Linde-Flaherty, who was helping transfer the patient to the x-ray table, leaned across the control panel of the x-ray machine and inadvertently hit the joystick that controlled the movement of the C-arm.⁴ (Id. Ex. D-1.) The activation of the joystick rotated the C-arm into Ehlers's right foot. (Id.) The hospital staff had been notified of this patient's arrival thirty minutes before. (Id. Ex. A-1 at 57, 59-60.) Linde-Flaherty, Coombs, Dr. Burke, and Dr. Wang had received training on the operation and safety of the x-ray machine and were in the lab on this day. (Id. Ex. A-10; Ex. C at ¶ 10; Exs. C-1, C-2.) At the time of Ehlers's injury, the C-arm of the x-ray machine was not in the "patient transfer position." (Id. at 70-71, 79-80; Ex. D.)

In July 2006, Ehlers filed this product-liability action in Minnesota state court, which Siemens removed to this Court. Siemens now moves to exclude the proposed testimony of Barry N. Feinberg, Ph.D., Ehlers's expert witness, under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 589 (1993), and for summary judgment.

STANDARD OF DECISION

Summary judgment is proper if, drawing all reasonable inferences in favor of the nonmoving party, there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); Celotex Corp. v. Catrett,

⁴ Ehlers does not know how the machine moved. Dr. Burke testified that he saw Linde-Flaherty inadvertently "lean into and push" the joystick on the control panel, which rotated the C-arm in its usual direction for this type of joystick motion. (Hirtz Aff. Ex. D-1.) The Court notes that there is no evidence that the x-ray machine malfunctioned such that it moved on its own and Ehlers makes no such claim. (Id.; Ex. A-21 at 56.)

477 U.S. 317, 322-23 (1986). The moving party bears the burden of showing that the material facts in the case are undisputed. Celotex, 477 U.S. at 322; Mems v. City of St. Paul, Dep't of Fire & Safety Servs., 224 F.3d 735, 738 (8th Cir. 2000). The Court must view the evidence, and the inferences that may be reasonably drawn from it, in the light most favorable to the nonmoving party. Graves v. Ark. Dep't of Fin. & Admin., 229 F.3d 721, 723 (8th Cir. 2000); Calvit v. Minneapolis Pub. Schs., 122 F.3d 1112, 1116 (8th Cir. 1997). The nonmoving party may not rest on mere allegations or denials, but must show through the presentation of admissible evidence that specific facts exist creating a genuine issue for trial. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986); Krenik v. County of Le Sueur, 47 F.3d 953, 957 (8th Cir. 1995).

ANALYSIS

Ehlers's Complaint does not set forth separate causes of action, but asserts claims sounding in negligence, breach of warranty, and strict liability for design defect, manufacturing defect, and failure to warn. (Compl. ¶¶ 4-11.) "Minnesota law merges negligence, design defect, and breach of warranty claims under a unified theory of strict product liability." Rosholt v. Blaw-Know Const. Equip. Corp., Civ. No. 04-1181, 2006 WL 839505, at *2 (D. Minn. March 29, 2006) (citing Bilotta v. Kelley Co., 346 N.W.2d 616, 623 (Minn.1984)). The Court notes, however, that Ehlers only addresses her strict-liability claim for design defect in her opposition Memorandum; the Court concludes that she has abandoned her claims for strict liability for manufacturing defect and failure to warn. See, e.g., Thomsen v. Ross, 368 F. Supp. 2d 961, 974 n.9 (D. Minn. 2005) (finding

that plaintiff had abandoned claims not addressed in his summary-judgment submissions).

I. Defective Design

In order to survive summary judgment on her defective-design claim, Ehlers must establish a genuine issue of material fact as to whether (1) the x-ray machine was in a defective condition that rendered it unreasonably dangerous to her; (2) the defect existed when it left Siemens's control; and (3) the defect was the proximate cause of her injuries. Westbrock v. Marshalltown Mfg. Co., 473 N.W.2d 352, 356 (Minn. Ct. App. 1991) (citing Bilotta, 346 N.W.2d at 623 n.3). Siemens argues that Ehlers has failed to establish the first and third elements.

To determine whether a particular product is unreasonably dangerous, the Court applies the "reasonable care balancing test." Bilotta, 346 N.W.2d at 621-23. This test focuses on whether the manufacturer has exercised "that degree of care in [the] plan or design so as to avoid any unreasonable risk of harm to anyone who is likely to be exposed to the danger when the product is used in the manner for which the product was intended, as well as unintended yet reasonably foreseeable use." Id. at 621. The Court must balance "the likelihood of harm, and the gravity of harm if it happens, against the burden of the precaution which would be effective to avoid the harm." Id. (quoting Holm v. Sponco Mfg., Inc., 324 N.W.2d 207, 212 (Minn. 1982)). An important factor in this balancing test is "evidence of the existence of a feasible, alternative safer design." Kallio v. Ford Motor Co., 407 N.W.2d 92, 96 (Minn. 1987).

Ehlers argues that the x-ray machine was unreasonably dangerous because it lacked certain safety devices. (Pl.'s Opp'n Mem. at 8-13.) To support her claim, she relies on Dr. Feinberg's proposed testimony.⁵ In arriving at his opinion, Dr. Feinberg reviewed various documents relating to the x-ray machine, including the operator's manual as well as the depositions and statements taken during discovery. (*Id.* at 2.) He also inspected the x-ray machine and watched Siemens's video showing it in operation. (*Id.*) From this, he wrote a report outlining his proposed testimony. (*Id.*)

Dr. Feinberg opined that the x-ray machine was defectively designed and unreasonably dangerous because it "did not have adequate collision protection nor audible alerts when the C-arm is in motion." (Hirtz Aff. Ex. A-22 at 4.). He indicated that medical personnel were at risk of being struck by the moving C-arm when their job functions took them between the C-arm and a fixed object such as a gurney or the x-ray table during a patient transfer. (Feinberg Aff. ¶ 4.) He referred to this as a "pinch point" hazard.⁶ (*Id.* ¶ 4.) He acknowledged that Siemens's x-ray machine had collision-detection sensors (touch-point sensors were located on the intensifier/flat detector and

⁵ Dr. Feinberg works at the Center for Engineering Analysis in Chicago, Illinois and serves as an international professional engineering consultant for universities, hospitals, industries, insurance companies, and the legal profession. (Feinberg Aff. ¶ 1.) He has graduate degrees in engineering and undergraduate degrees in electrical engineering and applied-engineering mathematics. (*Id.*) Previously, he was a tenured professor of Electrical and Computer Engineering at Purdue University where he authored the university textbook, *Applied Clinical Engineering*. (*Id.* at 1-2.) One of the chapters in the textbook was titled "Engineering Principles of Medical X-Ray Systems." (Sieben Aff. Ex. A-11.) There is no evidence that Dr. Feinberg discussed safety devices for an x-ray machine with a C-arm in his textbook. (*Id.*) Nor did he ever do any design or engineering work on an x-ray machine with a C-arm. (*Id.* Ex. A-21 at 8.)

⁶ Siemens had placed a small warning decal at the bottom of the C-arm which advised of the possible crushing danger. (Sieben Aff. Ex. A-10 at 3-4.)

collimator of the C-arm) that would automatically stop the movement of the C-arm when the sensors were contacted. (Sieben Aff. Ex. A-10 at 4.) Dr. Feinberg, however, believed that “[t]he problem with this type of collision detection system is that there are still areas on the moving C-arm that do not have collision detection and therefore can cause a crush injury to a person in the path of the C-arm, as it did to Ms. Ehlers.” (Id.) Dr. Feinberg opined in his report that the x-ray machine could have been made safer by using an audible alarm and appropriate collision-detection devices. (Id.) He did not, however, conduct any testing or elaborate further on his proposed safety modifications.

At his deposition, Dr. Feinberg elaborated on his conclusions and stated that his proposed collision-detection devices would “consist of sensors that detect the presence of a mass in the trajectory or path of the moving C-arm.” (See Feinberg Aff. ¶ 5; Hirtz Aff. Ex. A-21 at 62-70.) He explained that such devices were commonly used in other settings like a garage door that “uses a light beam to detect whether an object has entered the path of the closing garage door.” (Feinberg Aff. ¶ 5.) He also proposed that the x-ray machine have a collision detection sensor in the electric motor that powers the C-arm’s movement. (Id.) He explained that this type of sensor would rapidly measure the amount of electric current passing through the motor that powers the C-arm’s movement. “When the C-arm itself encounters an object in its path, the amount of electrical current needed to continue the forward motion of the C-arm throughout its range is increased.” (Id.) If the sensor detected an increase in demand current then it would send a signal to stop and/or reverse the C-arm’s movement. (Id.) Finally, Dr. Feinberg proposed that the x-

ray machine be equipped “with an audible warning alarm that warns medical personnel that the C-arm is in motion.” (*Id.*) In Dr. Feinberg’s opinion, Ehlers’s injury would not have occurred if the x-ray machine had been designed as he proposed. Siemens responded by asserting that Dr. Feinberg’s proposed testimony is unreliable and should be excluded.

II. Reliability of an Expert

The admissibility of expert testimony in this case is governed by Rule 702 of the Federal Rules of Evidence which provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The party offering expert testimony has the burden to prove its admissibility under Rule 702. Lauzon v. Senco Prods., Inc., 270 F.3d 681, 686 (8th Cir. 2001). Siemens does not claim that Dr. Feinberg is unqualified to render an opinion, but rather that his opinion is unreliable and of no assistance to the trier of fact.

This Court acts as a “gatekeeper” in screening expert testimony for reliability and relevance. Daubert, 509 U.S. at 589. In Daubert, the Supreme Court identified a number of factors that a district court may consider in assessing reliability: (1) whether the alternative design “can be (and has been) tested,” (2) whether it “has been subject to peer review and publication,” (3) “the known or potential rate of error,” and (4) whether it is

generally accepted in the relevant scientific community. Id. at 593-94. “This evidentiary inquiry is meant to be flexible and fact specific, and a court should use, adapt, or reject Daubert factors as the particular case demands.” Unrein v. Timesavers, Inc., 394 F.3d 1008, 1011 (8th Cir. 2005).

A. Testing

Dr. Feinberg opined that the x-ray machine is defective because it does not have (1) adequate collision-detection devices and (2) an audible alarm that alerts medical staff when the C-arm is moving. Siemens asserts that his proposed testimony should be excluded because it does not satisfy any of the Daubert factors. (Def.’s Mem. at 26-29.) The Court first addresses whether Dr. Feinberg’s proposed safety modifications can be, and have been, tested. See Daubert, 509 U.S. at 593. Testing is an important factor in analyzing the reliability of alternative design proposals. Peitzmeir v. Hennessy Indus., Inc., 97 F.3d 293, 296-98 (8th Cir. 1996). The Eighth Circuit has held that it is appropriate for district courts to exclude expert testimony involving proposed design changes that have never been developed or tested. See, e.g., Giles v. Miners, Inc., 242 F.3d 810, 812-13 (8th Cir. 2001) (affirming the exclusion of expert’s testimony because “there was no indication that [the expert] had analyzed how the proposed safety guard would interact with the freezers’ proper functioning”); Jaurequi v. Carter Mfg. Co., Inc., 173 F.3d 1076, 1084 (8th Cir. 1999) (affirming the exclusion of expert’s testimony because expert did not attempt to draw or construct safety device, “much less test its utility as a safety device or its compatibility” with the machine’s proper function).

Here, Dr. Feinberg asserts that the x-ray machine could have been made safer by utilizing infrared technology, a commonly used device in garage doors, but he did not conduct any testing to determine whether such a design was feasible with an x-ray machine that has a C-arm. Nor did he prepare drawings showing how it would be integrated into Siemens's x-ray machine or present photographs showing its use with similar machines. See Dancy v. Hyster Co., 127 F.3d 649, 651-52 (8th Cir. 1997) (affirming the exclusion of expert's testimony because he had not designed proposed safety device or pointed to its use on similar machines).

Dr. Feinberg also asserts that the x-ray machine could have been made safer by placing a sensor in the C-arm's motor such that it would stop and/or reverse the C-arm's path if it detected an increased demand for electric current. He indicated that General Electric ("G.E.") has a patent on this technology, but offered no further analysis or independent verification that such technology could be incorporated into Siemens's x-ray machine. (Feinberg Aff. ¶¶ 2, 5.) Indeed, the x-ray machine depicted in the G.E. patent is different and smaller than the x-ray machine in this case. (Sieben Aff. Ex. B.) Furthermore, there is no evidence that G.E. has actually incorporated the technology into any of its x-ray machines or that this technology existed at the time Siemens manufactured its x-ray machine. See Pestel v. Vermeer Mfg. Co., 64 F.3d 382, 384 (8th

Cir. 1995) (affirming the exclusion of expert's testimony on proposed safety device for stump remover because it had never been tested or developed).⁷

Dr. Feinberg provided even less information about his proposed audible alarm. Other than pointing out this feature in his report, he has done no research or testing on the utility and/or feasibility of such an alarm. He offered no opinion as to what the volume, pitch or frequency of the proposed alarm should be. Furthermore, he failed to perform any investigation or testing to determine whether Ehlers would have had enough time to move out of the way once the proposed alarm was activated. "An expert proposing safety modifications must demonstrate by some means that they would work to protect the machine operators but would not interfere with the machine's utility." See Unrein, 394 F.3d at 1012.

Dr. Feinberg acknowledged "that courts of law may want to be assured that any modified design suggestion has practical functionality." (Feinberg Aff. ¶ 6.)

Nonetheless, he argued that testing was not required in this case because:

[w]hen man first traveled to the moon it was made possible by engineers who used scientific and engineering knowledge to anticipate the function of each piece of equipment necessary to the task of safely conveying a man to

⁷ Dr. Feinberg also references another G.E. patent that purportedly accomplished the same goal as the previous G.E. patent, but in a different way. (Feinberg Aff. ¶ 2.) He then references a patent obtained by Phillips Electronics that purportedly "uses force sensors to detect x-ray machine C-arm collision." (Id.) Other than this cursory discussion, he did not elaborate any further or distinguish the differences in this technology compared to the collision-detection sensors on Siemens's x-ray machine. He also points to a handful of x-ray manufacturer websites, without any analysis or explanation. (Id.) None of the websites discusses the technology Dr. Feinberg proposes or that such technology was available before Siemens manufactured and sold its x-ray machine. Finally, Dr. Feinberg references the table of contents of his textbook, which makes no reference to C-arms or his proposed safety modifications.

a lunar orbit . . . [but] they were not able to ‘test’ the product first on the moon. They accomplished this by utilizing scientific predictions to anticipate issues and design responses to each potential contingency and then design an acceptable and safe response.

Id. Yet, these statements only undercut his position. See Stanczyk v. Black & Decker, Inc., 836 F. Supp. 565, 568 (N.D. Ill. 1993) (“the history of engineering and science is filled with finely conceived ideas that are unworkable in practice.”) Indeed, they reveal why an expert’s testing, at least in some form, is so important in a case like this where an engineer is brought in to opine that a product should have been designed differently. Here, a jury would have to be presented with evidence of whether the proposed safety modifications could easily have been incorporated into Siemens’s x-ray machine when it was manufactured and sold in 2003, and whether such alteration would have had a negative impact on the x-ray machine’s safety or performance.

While experts are not required to manufacture a new device or prototype, the expert must demonstrate by some means that the proposed safety designs are feasible and compatible with the machine’s proper function. Unrein, 394 F.3d at 1012 (expert’s opinion must be “sufficiently grounded”). Dr. Feinberg, however, has done nothing more than criticize an existing design and imagine a safer machine. Watkins v. Telsmith, Inc., 121 F.3d 984, 992 (5th Cir. 1997) (“[T]he proper methodology for proposing alternative designs includes more than just conceptualizing possibilities. The district court appropriately noted the lack of testing of any of the proposed alternatives”); see also Dhillon v. Crown Controls Corp., 269 F.3d 865, 870 (7th Cir. 2001) (noting that many alternative design considerations “are product and manufacturer-specific and cannot be

reliably determined without testing”). Ehlers has failed to demonstrate that Dr. Feinberg’s proposed safety designs are feasible and compatible with the x-ray machine’s proper function – they are speculative at best. Accordingly, the Court determines that Dr. Feinberg’s lack of testing weighs heavily against the admissibility of his testimony.

B. Peer Review and Publication

The second relevant factor for the Court to consider is whether Dr. Feinberg’s proposed safety modifications have been subjected to peer review and publication. See Daubert, 509 U.S. at 593. The “submission to the scrutiny of the scientific community is a component of ‘good science,’ in part because it increases the likelihood that substantive flaws in methodology will be detected.” Id. Dr. Feinberg does not specifically address how each of his proposed safety modifications has been subjected to peer review and publication; he simply asserts that his proposed safety modifications have practical application in the “real world” and generally refers to the patents referenced above. (See Feinberg Aff. ¶¶ 5-6; Pl.’s Opp’n Mem. at 13.)

In the Court’s view, this will not suffice. There is no evidence of peer review and publication of Dr. Feinberg’s proposed infrared sensor and audible alarm. Ehlers attempts to explain the dearth of peer review and publication by referring to the patents. The process of peer review and publication is the usual manner in which alternative designs are rigorously scrutinized and verified. The patents, however, do not “subject” these alternative designs to any meaningful “peer review” because they have not been scrutinized by others in the industry to determine if the designs are safe or practical.

Indeed, Dr. Feinberg did not participate in the development of these patents and he did not supervise any testing to determine their feasibility. Moreover, Dr. Feinberg did not consult others in the industry or submit his proposed safety modifications to any manufacturers for scrutiny. See Pestel, 64 F.3d at 384. Therefore, the Court determines that this factor also weighs against the admissibility of Dr. Feinberg's proposed testimony.⁸

C. General Acceptance

Next, the Court considers the general acceptance of Dr. Feinberg's proposed safety modifications. "Widespread acceptance can be an important factor in ruling particular evidence admissible, and 'a known technique which has been able to attract only minimal support within the community 'may properly be viewed with skepticism.'" Daubert, 509 U.S. at 594 (citation omitted). Dr. Feinberg asserts that his proposed infrared sensor has been generally accepted due to its "common use on a variety of moving products," including a garage door. (Feinberg Aff. ¶ 5.) With respect to his proposed collision-detection devices, he references the patents as being in the public domain. (Id.) He also asserts that his proposed audible alarm has been generally accepted because "[a]udible warnings have long been used in machine operation" including the x-ray machine in this case. (Id.)

⁸ The Court will not consider the third Daubert factor – known or potential rate of error – because it is not relevant here. See Pestel, 64 F.3d at 384. Indeed, there can be no error rate when Dr. Feinberg failed to conduct any testing of his proposed designs. See Peitzmeier, 97 F.3d at 297 (excluding proposed design while noting that because it had not been designed or tested, it could not be subjected to peer review or evaluated for rate of error).

Such vague and conclusory assertions fall short of the “generally accepted” factor set forth in Daubert. Needless to say, because Dr. Feinberg’s alternative designs have not been tested or subjected to peer review and publication, it necessarily follows that his proposed designs have not been generally accepted in the industry. There is no evidence that Dr. Feinberg’s proposed safety modifications are being used by any other manufacturer of x-ray machines with C-arms for the purposes articulated by Dr. Feinberg. Ehlers has failed to meet her burden of demonstrating that Dr. Feinberg’s alternative designs have been generally accepted in the industry. Accordingly, this factor weighs against the admissibility of his testimony.

D. Other Factors

Cases decided after Daubert provide additional factors for determining the reliability of an expert’s proposed testimony, including whether the expert’s opinion or methodology were developed solely in a litigation context and “whether the proposed expert ruled out other alternative explanations.” Lauzon, 270 F.3d at 687 (citations omitted). Here, Dr. Feinberg’s proposed alternative designs were developed solely for purposes of testifying in this case. There is no evidence that he researched, tested, analyzed or even discussed his proposed safety designs for x-ray machines with C-arms prior to this case. See, e.g., Samuel v. Ford Motor Co., 96 F. Supp. 2d 491, 503 (D. Md. 2000) (excluding expert’s alternative design because it was “born in litigation” and therefore unreliable). This further increases the unreliability of his opinion. In addition, Dr. Feinberg failed to even consider alternative causes for Ehlers’s accident. In

particular, his expert report disregards the fact that the hospital failed to move the x-ray machine to the patient-transfer position, as instructed by Siemens.⁹ Notably, Dr. Feinberg conceded at his deposition that this accident would not have happened if the x-ray machine was in the patient-transfer position. (Hirtz Aff. Ex. A-21 at 105-06.) In the Court's view, this is another factor that demonstrates the unreliability of Dr. Feinberg's testimony. See Kumho Tire Co., Ltd., v. Carmichael, 526 U.S. 137, 153-54 (1999) (rejecting plaintiff's expert's opinion that the tire separated due to a manufacturing defect because expert disregarded evidence that tire bore marks of abuse, had been inadequately repaired for punctures, and should have been taken out of service).

In the end, Dr. Feinberg's conclusions are connected to the existing data by his own unsupported assertions. General Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). Based on the foregoing, and after carefully examining Dr. Feinberg's expert report, the Court concludes that his proposed testimony is not sufficiently reliable under Daubert and, as a result, must be excluded. Without the testimony of Dr. Feinberg, Ehlers's defective-design claim cannot survive summary judgment as she has proffered no other evidence that the x-ray machine was in a defective condition which rendered it unreasonably dangerous. Nonetheless, even if Dr. Feinberg's proposed testimony were deemed admissible, the defective-design claim would fail as a matter of law because she cannot show that the alleged design defect was the proximate cause of her injury.

⁹ Nor did he discuss the fact that the hospital staff failed to move the control panel away from the x-ray table so as to avoid any inadvertent movement of the C-arm.

III. Proximate Cause

“Generally, proximate cause is a question of fact for the jury; however, where reasonable minds can arrive at only one conclusion, proximate cause is a question of law.” Lubbers v. Anderson, 539 N.W.2d 398, 401 (Minn. 1995). The causation standard for product-liability claims is not different from the standard applied in ordinary negligence cases. In negligence cases, the defendant’s negligent conduct must have been a substantial factor in bringing about the injury. See, e.g., Canada v. McCarthy, 567 N.W.2d 496, 506 (Minn. 1997). Thus, Ehlers must proffer sufficient admissible evidence from which a jury could conclude that the purported design defect in the x-ray machine was a substantial factor in bringing about her injury. An intervening act, however, may break the causal connection between the alleged design defect and Ehlers’s injury such that it constitutes a superseding cause and insulates Siemens from liability. Lofgren v. Pieper Farms, 540 N.W.2d 834, 837 (Minn. 1995). An intervening act is a superseding cause when four elements are satisfied: (1) its harmful effects happened after the design defect; (2) it must not have been brought about by the design defect; (3) it changed the natural course of events and made the result different from what it would have been; and (4) the manufacturer could not have reasonably anticipated this event. Canada, 567 N.W.2d at 507.

Here, there is no dispute that the harmful effects of the hospital staff’s negligence in failing to put the x-ray machine in the patient-transfer position occurred after Siemens’s alleged design defect. Next, there is no evidence that the hospital staff’s

negligence was brought about by Siemens's alleged design defect. Siemens provided extensive training to the hospital staff on the operation and safety features of the x-ray machine. Most notably, Siemens instructed the hospital staff that the x-ray machine should be placed in the patient-transfer position when transferring a patient to an x-ray table. It is clear that the hospital staff did not follow these instructions at the time of this incident because the x-ray machine was in close proximity and in line with the x-ray table. Simply put, the hospital staff failed to move the x-ray machine away from the x-ray table and into the patient-transfer position as instructed by Siemens.

It is also undisputed that Ehlers's injury would not have occurred if the hospital staff had put the x-ray machine in the patient-transfer position. When the C-arm of the x-ray machine is in the patient-transfer position, it is six feet away from the head of the x-ray table.¹⁰ Further, the technicians and physicians who were trained on the safety of the x-ray machine had ample time to put it in the patient-transfer position before the patient arrived at the hospital. Notably, the expert witnesses for both parties agreed that Ehlers's injury would not have occurred if the x-ray machine was in the patient-transfer position. (See Hirtz Aff. Ex. D-1 at 4-5; Ex. A-21 at 105-06.) Thus, the hospital staff's negligence in failing to put the x-ray machine in the patient-transfer position changed the natural

¹⁰ The Court notes that if the x-ray machine had been in the patient-transfer position any inadvertent contact with the joystick could not have resulted in Ehlers's injury. It is also undisputed that the control panel on which the joystick was mounted was left in a position that required leaning and lifting the patient up and over the controls for any inadvertent contact with the joystick to occur. Siemens specifically instructed the hospital staff that it may be necessary to move the control console during a patient transfer to make sure no unit movements were initiated inadvertently. Ehlers's injury would not have occurred if the hospital staff had followed either one of these instructions.

course of events and destroyed any causal connection between Siemens's alleged design defect and Ehlers's injury.

Finally, the hospital staff's failure to follow the training and instruction manual for conducting a patient transfer was not reasonably foreseeable. Indeed, "failure to follow proper instructions and the manufacturer's directions [for use of the product] may constitute unforeseeable misuse" and relieve the manufacturer of liability. See Rosholt, 2006 WL 839505, at *3; see also Roberts v. Donaldson, 149 N.W.2d 401, 408 (Minn. 1967) (truck driver's negligence in failing to observe highway instructions and signs regarding route to be driven was a superseding cause relieving tractor owner of liability); Hood v. Ryobi Am. Corp., 181 F.3d 608, 612 (4th Cir. 1999) (applying Maryland law) (manufacturer need not anticipate that a user will ignore clear warnings).

In Rosholt, the plaintiff's foot was severed by a paving machine in an on-the-job accident. 2006 WL 839505, at *1. The manufacturer of the paver specifically warned users "not to start the engine by shorting across starter terminals" and the operator's manual instructed users to make sure that "the hand brake is set and the transmission shift lever, direction-speed control lever and all switches are in the 'OFF' or neutral positions before starting the engine." Id. at *4. The plaintiff disregarded the manufacturer's instructions. The District Court held that the plaintiff's design-defect claim failed as a matter of law and entered summary judgment in favor of the manufacturer. The District Court reasoned that "[p]laintiff was a trained and experienced mechanic who understood the significance of these warnings. He could easily have followed them . . . [and] [h]ad

he followed even a single one of these known safety procedures, or many other precautions recommended in the manuals, this accident would not have occurred.” Id.

Likewise, it was not reasonably foreseeable that the hospital staff, which had received extensive training on the operation and safety of the x-ray machine and were in the lab on the day of Ehlers’s injury, would fail to follow these directions. Indeed, if the hospital staff had followed “the known safety procedures . . . this accident would not have occurred.” Id. This failure to follow the training and instructions it had received from Siemens was a superseding cause which broke any causal connection between Siemens’s alleged design defect and Ehlers’s injury. Accordingly, Ehlers’s design-defect claim fails as a matter of law.

CONCLUSION

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS ORDERED** that Siemens’s Motion for Summary Judgment (Doc. No. 43) is **GRANTED** and Ehlers’s Complaint (Doc. No. 1) is **DISMISSED WITH PREJUDICE**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Date: April 15, 2008

s/Richard H. Kyle
RICHARD H. KYLE
United States District Judge